

[Federal Register: December 9, 1998 (Volume 63, Number 236)]
[**Proposed** Rules]
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[DOCID:fr09de98-21]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 334

[Docket No. 78N-036L]
RIN 0910-AA01

Laxative Drug Products for Over-the-Counter Human Use; Partial
Withdrawal of **Proposed** Amendment to the Tentative Final Monograph;
Intent to Repropose

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of **proposed** rulemaking; withdrawal in part and intent to
repropose.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing that
part of the notice of **proposed** rulemaking that would have amended the
tentative final monograph for over-the-counter (OTC) **laxative** drug
products to include additional professional labeling for oral and
rectal dibasic sodium phosphate/monobasic sodium phosphate (sodium
phosphates) drug products. The agency intends to repropose the
professional labeling for these products in a future issue of the
Federal Register.

FOR FURTHER INFORMATION CONTACT: Gloria Chang, Center for Drug
Evaluation and Research (HFD-560), Food and Drug Administration, 5600
Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 21, 1998 (63
FR 27886), FDA published an amendment to the tentative final monograph
for OTC **laxative** drug products proposing to include additional general
labeling and expanded professional labeling for oral and rectal sodium
phosphates drug products. The agency **proposed** to expand the
professional labeling for products containing sodium phosphates in
Sec. 334.80(b)(2) of the tentative final monograph for OTC **laxative**
drug products (50 FR 2124 at 2157, January 15, 1985). The agency also
proposed a new format using specific headings to make the **proposed**
professional labeling information clearer and more readable. Interested
persons were invited to submit written comments or objections by August
19, 1998.

The agency plans to further expand the professional labeling in
proposed Sec. 334.80(b)(2). This notice is to inform interested persons
that the agency is withdrawing the **proposed** amendment to the OTC
laxative tentative final monograph for professional labeling for
products containing sodium phosphates in Sec. 334.80(b)(2) and will be
reproposing the professional labeling in a future issue of the Federal

Register. Further, this partial withdrawal of the **proposed** amendment to the OTC **laxative** tentative final monograph does not affect the current marketing status of sodium phosphates drug products.

The agency has determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This withdrawal notice is issued under authority of 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

Dated: December 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-32642 Filed 12-8-98; 8:45 am]

BILLING CODE 4160-01-F